AWARD NUMBER: W81XWH-14-1-0368

TITLE: Addressing the Health Concerns of VA Women with Sexual Trauma

PRINCIPAL INVESTIGATOR: Caron Zlotnick, PhD

CONTRACTING ORGANIZATION: WOMEN & INFANTS HOSPITAL OF RHODE ISLAND
PROVIDENCE, RI 02905-2401

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PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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Caron Zlotnick, PhD

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14. ABSTRACT

Lifetime ST disproportionately affects women veterans and can threaten their health and wellbeing. PTSD, IPV, and alcohol use are closely interrelated and significant concerns for women veterans with lifetime ST. Providing effective and low-cost interventions to address ST-related risks among women veterans with lifetime ST would advance clinical care for these women in an important area.

15. SUBJECT TERMS-

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	8	19b. TELEPHONE NUMBER *(include area code)*

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1. INTRODUCTION:

Our proposed research will develop and assess a computer-delivered intervention (Safety and Health Experiences Program; SHE) that will provide a screening and brief behavior intervention for women veterans with any lifetime ST**.** More specifically, the intervention, SHE, will address interrelated health concerns for women veterans with ST (i.e., alcohol misuse, IPV, and PTSD). We plan to develop our proposed computer-based intervention with input from our team of investigators as well as information gained in focus groups and informant interviews with women veterans with ST. We will conduct a small trial of SHE with 20 women veterans with lifetime ST to examine if the intervention is acceptable to our population. Finally, we will recruit a sample of 150 women veterans who screen positive for any lifetime ST and have at least one risk factor (i.e., IPV, PTSD, or heavy drinking) and randomize them to the SHE intervention or to a screen and referral (SR) condition. We will examine whether SHE compared to SR will result in decreases in the number of risks and increase resource and treatment utilization at the 2- and 4-month follow-up.

2. KEYWORDS:

Safety and Health Experiences Program; SHE
Sexual Trauma (ST)
Intimate Partner Violence (IPV)
Posttraumatic Stress Disorder (PTSD)
Screen and referral (SR)
Data Safety Monitory Board (DSMB)

3. ACCOMPLISHMENTS:

1. Staff has been hired and trained.
2. Study materials have been purchased and study databases and tracking files have been prepared.
3. All regulatory approvals have been obtained.
4. Tables for the Data Safety Monitory Board (DSMB) report have been prepared, a medical monitor (MM) for the study has been appointed, the DSMB has met and approved the report tables, study consents, study safety procedures, and study recruitment procedures.
5. A preliminary outline of the computer-based intervention modules (3) has been developed.

In the next reporting period we plan to recruit for and conduct informant interviews to inform and refine the intervention.

"Nothing to report" on training and professional development opportunities and the dissemination of results to communities of interest.

4. IMPACT:

Nothing to Report.

5. CHANGE/PROBLEMS:

The following amendments have been submitted and approved by the IRBs of Central Texas Veterans Health Care System and by Woman and Infants Hospital

- The screening measure for PTSD (PCL-M and PCL-C) was replaced with PCL-5. The PLC-5 will be used because it is the measure of PTSD symptoms that is currently being used in Veteran Administration settings and other research on PTSD with Veterans.
- Removed the intervention feedback measures of Drinker Inventory of Consequences and Brief Drinker Profile for intervention participants. We will use other forms of participant feedback for the alcohol intervention module.
- Included the option to do assessments over the phone if participants are unable to meet in person. This will allow the collection of follow-up data from women who cannot come to the VA hospital
- Focus groups were changed to individual informant interviews.) We changed focus groups to individual informant interviews. It will be difficult to coordinate a group of women for the focus group because the women's competing demands for time and their infrequent visits to the VA primary care center.
- We changed the Breathalyzer procedure to be administered only if the potential participant shows signs of intoxication

Since the VA mandates that women provide consent to be breathalyzed and be seen at an emergency room if intoxicated, we wish to reduce this burden and reduce the barriers and stigma to women who may benefit from participating in our study.

Actual or anticipated problems or delays and actions or plans to resolve them:

The award was received in March 2016. The subcontract was executed to Central Texas VA Healthcare System at Temple in May 2016. Advertising, interviewing, and hiring of a research assistant with a start date of 3rd of August 3 was completed in two months.

6. PRODUCTS:

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGNIZATIONS:

The following individuals have worked on the project.

Name:	*Caron Zlotnick*
Project Role:	*Principle Investigator*
Researcher Identifier (e.g. ORCID ID):	*none*
Nearest person month worked:	*3*
Contribution to Project:	*Dr. Zlotnick*
Funding Support:	In-kind

Name:	*Suzannah Creech*
Project Role:	*Co-I/Site PI*
Researcher Identifier (e.g. ORCID ID):	0000-0002-6582-1673
Nearest person month worked:	*2.4*
Contribution to Project:	*Oversees all project tasks and personnel at the Central Texas site of the project.*
Funding Support:	*VHA VISN 17 Center of Excellence*

Name:	*Elaine Brown*
Project Role:	*Research Technician*
Researcher Identifier (e.g. ORCID ID):	*none*
Nearest person month worked:	*4.8*
Contribution to Project:	*Ms. Brown assisted with all IRB paperwork and other key administrative tasks.*
Funding Support:	*VHA VISN 17 Center of Excellence*

Name:	*Jeisa Jones*
Project Role:	*Research Technician*
Researcher Identifier (e.g. ORCID ID):	*none*
Nearest person month worked:	*1*
Contribution to Project:	*Ms. Jones is the full time research technician on the study.*
Funding Support:	

There have been changes in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period.

Caron Zlotnick (PI)
The following grant has ended:
R21 HD07565 Tzilos and Zlotnick (Joint PIs) 8/2013 – 7/2016 2.04 calendar
NICHHD Computer Intervention for HIV/STI Risk and Drug Use during Pregnancy.

Tracie Shea (Co-I)
The following grant has started:
1 I01 RX001783-01A1 (Shea: PI) 01/01/16-12/31/19 4.20 calendar
Department of Veterans Affairs Interpersonal Therapy for Veterans with PTSD

Lindsay Orchowski (Co-I)
Preventing Sexual Aggression Among High School Boys
1U01CE002531-01 (Orchowski: PI) 9/1/14 – 8/31/18 4.56 CM
National Center for Injury Prevention and Control
Preventing sexual aggression among high school boys
Role: PI

Community-Level Primary Prevention of Dating and Sexual Violence in Middle Schools
1U01CE002651-01 (Orchowski: PI) 9/30/15-9/29/2019 4.8 CM
National Center for Injury Prevention and Control
Role: PI

Sexual Assault Prevention for Men in the Military (Orchowski, Kazemi, Caban: Joint PIs)
PT140100 10/1/15 – 9/30/19 3CM
CDMRP/Department of Defense
Role: Joint-PI/PD

The following grants have ended:

Integrated Alcohol and Sexual Assault Intervention for College Men
1R34AA020852-01 (Orchowski: PI) 9/20/2012-8/31/2015 4.56 CM
NIAAA
Role: PI

Chris Kahler (Co-I)
The following grants have started:
Behavioral Science and Biostatistics Resource Core for Alcohol-HIV Research
1U24AA022003 (Kahler: PI) 09/1/16-08/31/21 2.4 Calendar
NIAAA

Positive Psychotherapy for Smoking Cessation Enhanced with Text Messaging: A Randomized Controlled Trial
1R01CA201262-01A1 (Kahler: PI) 07/01/16-06/30/21 4.2 Calendar
NCI

The following grants have ended:
Minority Populations Resource Core
1U24AA022000 (Operario) 9/28/12-8/31/16 0.24 Calendar
NIAAA
Role: Co-I

Golfo Tzilos (Co-I)
The following grants have ended:
NICHHD Computer Intervention for HIV/STI Risk and Drug Use during Pregnancy R21
HD07565 Tzilos and Zlotnick (Joint PIs) 8/2013 – 7/2016 2.4 calendar

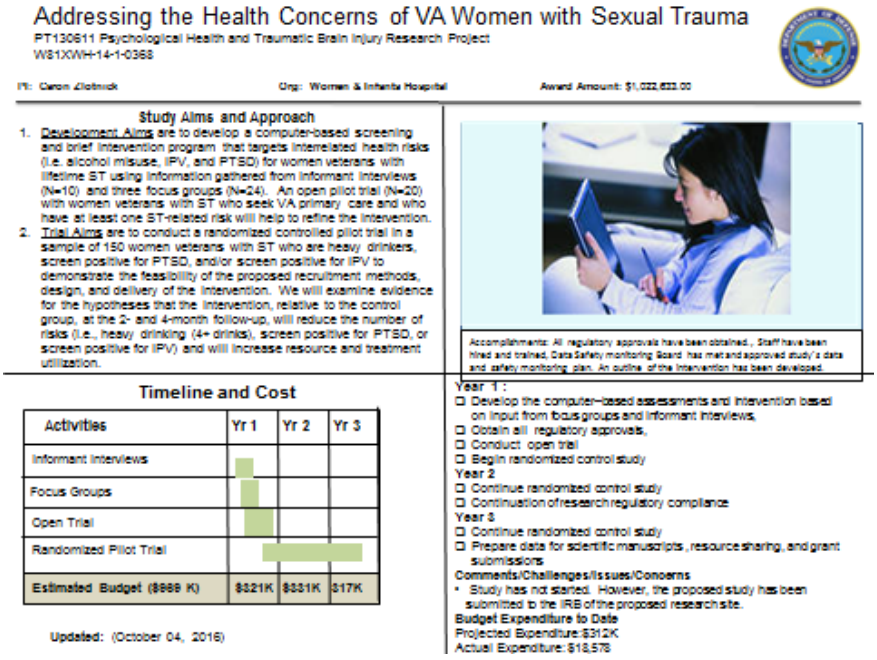
Computer-Based Intervention for Victimized Perinatal Women with Mental Illness
R21 HD077358 (PI Zlotnick) 04/1/14 – 03/31/16 1.2 Calendar
Role: Co-I

Suzannah Creech (Co-I; site PI)
The following grants have started:
Strength at Home Couples Program to Prevent Military Partner Violence
Department of Defense (Taft: PI) 09/15–09/19 .5 Calendar
Role: Co-I

Extension of the Implementation of VA Rollout of Strength at Home Bob Woodruff Foundation, (Taft: PI) 9/1/16-9/1/17 1.2 Calendar

Nothing to report regarding other organizations involved as partners

8. SPECIAL REPORTING REQUIREMENTS:



Addressing the Health Concerns of VA Women with Sexual Trauma

PT130611 Psychological Health and Traumatic Brain Injury Research Project
W81XWH-14-1-0368

PI: Caron Zlotnick Org: Women & Infants Hospital Award Amount: $1,022,833.00

Study Aims and Approach

1. Development Aims are to develop a computer-based screening and brief intervention program that targets interrelated health risks (i.e. alcohol misuse, IPV, and PTSD) for women veterans with lifetime ST using information gathered from informant interviews (N=10) and three focus groups (N=24). An open pilot trial (N=20) with women veterans with ST who seek VA primary care and who have at least one ST-related risk will help to refine the intervention.
2. Trial Aims are to conduct a randomized controlled pilot trial in a sample of 150 women veterans with ST who are heavy drinkers, screen positive for PTSD, and/or screen positive for IPV to demonstrate the feasibility of the proposed recruitment methods, design, and delivery of the intervention. We will examine evidence for the hypotheses that the intervention, relative to the control group, at the 2- and 4-month follow-up, will reduce the number of risks (i.e., heavy drinking (4+ drinks), screen positive for PTSD, or screen positive for IPV) and will increase resource and treatment utilization.

Timeline and Cost

Activities	Yr 1	Yr 2	Yr 3
Informant Interviews			
Focus Groups			
Open Trial			
Randomized Pilot Trial			
Estimated Budget ($969 K)	$321K	$331K	$317K

Updated: (October 04, 2016)

Accomplishments: All regulatory approvals have been obtained., Staff have been hired and trained, Data Safety monitoring Board has met and approved study's data and safety monitoring plan. An outline of the intervention has been developed.

Year 1 :
- ☐ Develop the computer-based assessments and intervention based on input from focus groups and informant interviews,
- ☐ Obtain all regulatory approvals,
- ☐ Conduct open trial
- ☐ Begin randomized control study

Year 2
- ☐ Continue randomized control study
- ☐ Continuation of research regulatory compliance

Year 3
- ☐ Continue randomized control study
- ☐ Prepare data for scientific manuscripts, resource sharing, and grant submissions

Comments/Challenges/Issues/Concerns
- Study has not started. However, the proposed study has been submitted to the IRB of the proposed research site.

Budget Expenditure to Date
Projected Expenditure: $312K
Actual Expenditure: $18,578

9. APPENDICES:

Nothing to Report.